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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/582,461	02/26/2008	Jee Loon Look	AM101358	2119
25291	7590	09/10/2010	EXAMINER	
WYETH LLC			HILL, MYRON G	
PATENT LAW GROUP				
5 GIRALDA FARMS			ART UNIT	
MADISON, NJ 07940			PAPER NUMBER	
			1648	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

~IPGSMadisonDocketing@pfizer.com

Office Action Summary	Application No. 10/582,461	Applicant(s) LOOK ET AL.	
	Examiner MYRON G. HILL	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 May 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) 43,46,48-50,54,55,60-63,86,105 and 122-124 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,5,6,8,11,13,18,22-25,30,33,35,37,41 and 42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 6/12/06 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>9/29/06</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims pending in the application are 1,3,5,6,8,11,13,18,22-25,30,33,35,37,41-43,46,48-50,54,55,60-63,86,105 and 122-124.

DETAILED ACTION

Claims 43,46, 48-50, 54, 55, 60-63, 86, 105, and 122-124 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 5/14/10.

This action is on claims 1, 3, 5, 6, 8,11,13,18, 22-25, 30, 33, 35, 37, 41, and 42.

Information Disclosure Statement

A signed and initialed copy of the IDS paper filed 9/29/06 is enclosed.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3, 5, 6, 8,11,13, 22-25, 30,33, 35, 37, 41, and 42 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is not clear what the metes and bounds are of the term "stable". There is no indication as to the level of stability that is required of the claims.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

Art Unit: 1648

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, 5, 6, 8, 11, 13, 18, 22-25, 30, 33, 35, 37, 41, and 42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The prior art teaches that PIV-4, Mumps and certain strains of RSV have been freeze dried (Tannock et al. from IDS) as well as Measles (Phillips, Cryobiology from IDS).

The prior art does not teach PIV-1 or 2, or metapneumoviruses. Metapneumovirus includes at least human, murine, and avian viruses.

Tannock et al. teach that different strains of RSV have different stability after freeze drying (Table 2).

The specification as filed fails the standard of written description. Applicants have provided a wish list and the disclosure fails to provide adequate teaching under the quid pro quo doctrine.

The goal of written description requirement is "to clearly convey the information that an applicant has invented the subject matter which is claimed", see In re Barker, 559 F.2d 588, 592 n.4 (CCPA 1977). The inventor has an obligation under "written description" to disclose the technologic knowledge upon which the patent is based and to demonstrate that the patentee was in possession of the invention that is claimed. See

Art Unit: 1648

Capon v. Eshhar, 418 F.3d 1349, 1357 (Fed. Cir. 2005). In the instant disclosure, Applicants have made broad statements and more or less a wish list for others to conduct research. Applicant cannot enjoy the fruit of excluding others from practicing the invention for a limited period of time without providing the public meaningful disclosure. See *Ariad Pharmaceuticals Inc. v. Eli Lilly & Co.*, 94 USPQ2d 1161 (Fed. Cir. 2010)

Here, Applicants' teaching are not commensurate with the scope of patent protection. Applicants were not in possession of methods that can freeze dry all the viruses claimed. The disclosure does not possess what it claims. The specification does not set forth the metes and bounds of that encompass, and there is not enough information about it in literature either to guide the one of ordinary skill in the art to predict the requirements to freeze dry metapneumovirus and PIV1 and 2. Thus, the disclosure fails to provide a meaningful disclosure and possession of the broad scope of the now claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Art Unit: 1648

Claims 1, 3, 5, and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Tannock et al. (from IDS).

Tannock et al. teach a stabilized freeze dried RSV sample in SPGA buffer (page 1769 column 2 and Table 2).

Tannock et al. is silent on the exact time of the freezing to glass transition temperature but the virus is stable for 45 weeks as indicated in Table 2.

Where, as here, the Patent Office lacks the facilities to perform comparisons between the claimed material and prior art materials that reasonably appear to meet the claim limitations, the burden is properly shifted to applicant to distinguish the claimed product from the prior art product. See *In re Best, Bolton, and Shaw*, 195 USPQ 430 (CCPA 1977); *Ex Parte Gray*, 10 USPQ2nd 1922 (BPAI 1989).

Thus, Tannock et al. anticipate the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3, 5, 6, 8, 11, 18, 22-25, 30, 33, 35, 41, and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tannock et al. (from IDS) and Parrington et al. (WO 02/09747 from IDS).

Art Unit: 1648

Tannock et al. teach a stabilized freeze dried RSV sample of 0.5ml in SPGA buffer, that a commercial freeze drying system was used, and that the freeze drying was done under vacuum and that nitrogen was added to the chamber and the ampoules were sealed (page 1769 column 2 and Table 2). Tannock et al. also teach that

Tannock et al. do not teach a variety of buffers or freeze drying conditions.

Parrington et al. teach that RSV proteins can be freeze dried and stabilized. The buffers include glutamic acid and sodium salts (Table 4). Table 5 teaches freezing to -50C at about 2C per min.

One of ordinary skill in the art at the time of invention would have been motivated to make a storage stable RSV composition because Tannock et al. teaches that RSV is difficult to handle in the laboratory and loses titer after freeze thaw cycles and transporting live virus or live vaccine needs a "cold chain" (page 1769, col 1). One of ordinary skill in the art at the time of invention would have been motivated to freeze different size sample volumes based on the use of the freeze dried sample after it is made.

One of ordinary skill in the art at the time of invention would have been motivated to various buffers and freeze drying protocols to achieve stable virus compositions with the expectation of success because Tannock et al. teaches that freeze dried compositions of RSV can be made.

Thus, it would have been prima facie obvious to modify the method of Tannock et al. with the steps of Parrington et al. with the expectation of success knowing that RSV can be freeze dried.

Claims 13 and 37 rejected under 35 U.S.C. 103(a) as being unpatentable over Tannock et al. and Parrington et al. as applied to claims 1, 3, 5, 6, 8, 11, 18, 22-25, 30, 33, 35, 41, and 42 above, and further in view of Suzuki.

Tannock et al. and Parrington et al. are discussed above.

They do not teach peptone.

Suzuki teaches that peptone is a stabilizer in freeze drying small pox according to Collier 1955 (page 29).

Suzuki does not teach soy peptone.

Heidemann et al. teach that soy peptone was available at the time of invention (page 159, col 1, top).

One of ordinary skill in the art at the time of invention would have been motivated to use peptone as a stabilizer because it is taught to be useful in stabilizing freeze dried virus. One of ordinary skill in the art at the time of invention would have been able to choose soy peptone from the available types.

Thus, it would have been prima facie obvious to use soy peptone in the method of Tannock et al. and Parrington et al. with the expectation of success knowing that it can stabilize freeze dried virus.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MYRON G. HILL whose telephone number is (571)272-0901. The examiner can normally be reached on M-Th and flex.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Zachariah Lucas can be reached on 571-272-0905. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mary E Mosher/
Primary Examiner, Art Unit 1648

/M. G. H./
Examiner, Art Unit 1648